

EXHIBIT 5



September 25, 2019

Via Electronic Mail

Special Master David Cohen
David R. Cohen Co. LPA
24400 Chagrin Blvd., Suite 300
Cleveland, OH 44122

Re: *In re: National Prescription Opiate Litigation*, MDL No. 2804
PEC's Submission – Challenges to Walgreens Privilege Claims

Dear Special Master Cohen:

On behalf of the Plaintiffs' Executive Committee ("PEC"), this submission sets-forth facts and Plaintiffs' arguments against application of privilege over various communications/documents being withheld by Walgreens. Aside from the fact that the documents at issue fall within the types previously determined not to be privileged, Walgreens has also waived any potential privilege by making affirmative claims that it has met all applicable regulatory obligations and/or believed that it met all such regulatory obligations.

Introduction

As an initial matter, the types of documents being challenged herein are the same types of documents previously ruled not to be privileged. These types of documents involve audit reports, audit findings, recommendations regarding same, SOMS details, SOMS work, and generally subjects which address compliance with regulatory obligations. Consistent with prior Discovery Rulings, these (and any similar) documents should be produced because they are not entitled to privileged treatment. Separately, even if any of these documents were determined to be privileged, Walgreens has waived privilege as a consequence of its various affirmative claims.

On the one hand, Walgreens has repeatedly asserted privilege over documents and testimony surrounding the details of: employees' knowledge of its distribution duties under the Controlled Substances Act ("CSA"), its suspicious order monitoring system ("SOMS"), and its SOMS efforts (e.g., policies, procedures, due diligence, suspicious order analysis, audits, etc.). On the other hand, Walgreens has, without disclosing all relevant documents and information, repeatedly asserted (in written discovery responses, deposition testimony, and affirmative defenses) that it has consistently met all applicable regulatory obligations. Walgreens has also put its corporate knowledge and/or state of mind at issue by asserting that its SOMS were based upon "its best understanding of DEA guidance" and/or "DEA's changing guidance".

When a party employs such tactics, it results in waiver of related privilege claims because the jurisprudence does not allow the attorney-client privilege to be used as a shield and as a sword. For example, Walgreens is not allowed to hide a communication which criticizes or negatively evaluates its SOMS, and simultaneously claim that it met all regulatory requirements. Similarly, Walgreens is not permitted to withhold information which details what it understood were its duties under the CSA, and at the same time claim it was uncertain of what the CSA required because the DEA was changing its guidance. Walgreens has made various affirmative claims which in fairness require examination of the allegedly protected communications. Otherwise, Walgreens is being allowed to impermissibly use privilege as a shield and as a sword.

Burden of Proof & Narrow Construction of Privilege

It is well established in the Sixth Circuit that: 1) the burden of establishing a privilege, including non-waiver, falls upon the party asserting it,¹ and 2) privileges are to be strictly confined within the narrowest possible limits.² Moreover, these burden of proof and narrow construction standards have even greater meaning in the context of the current matter because of the Court's prior Order regarding invoking of privilege claims relative to SOMS details.³

Prior Privilege-Related Discovery Rulings

As numerous prior rulings provide significant guidance relative to materials which should not remain privileged, the PEC will not re-hash all herein. However, the following principles from prior rulings are particularly applicable to the SOMS-related privilege claims at issue:

- “To be privileged, the communication must have the *primary* purpose of soliciting legal, rather than business, advice.”⁴

¹ *United States v. Dakota*, 197 F.3d 821, 825 (6th Cir.2000) (“The burden of establishing the existence of the privilege rests with the person asserting it.”). *See also, Davis v. Drake*, 2014 WL 5795554, at *4 (N.D. Ohio Nov. 6, 2014) (“The party claiming an attorney-client privilege not only bears the burden of proving that the privilege applies, but must also show that the privilege has not been waived.”); *Amway Corp. v. Proctor & Gamble Co.*, 2001 WL 1818698, at *4 (W.D. Mich. Apr. 3, 2001) (“The risk of non-persuasion arising from a failure to establish facts supporting a claim of privilege falls upon the party asserting it.”).

² “Claims of attorney-client privilege are ‘narrowly construed because [the privilege] reduces the amount of information discoverable during the course of a lawsuit.’” *In Re Columbia/HCA Healthcare Corporate Billing Practices*, 293 F.3d 289, 294 (6th Cir.2002) (quoting *United States v. Collis*, 128 F.3d 313, 320 (6th Cir.1997)). *See also*, DR 14-5 at p. 11.

³ On November 21, 2018, the Court entered an order which required in pertinent part that “Defendants shall not interpose attorney-client privilege as a reason for not producing discovery of all details of their SOMS. The Court will not allow defendants to rely at trial, in any motion, or for any other reason, upon any evidence of the existence or method of operation of a SOMS that is not produced by this date.” *See* Doc. #: 1147, at p. 1, ¶1. Although this Order has not been interpreted by the Special Master as wholly precluding the application of privilege, it has been interpreted to mean that privilege invocation with regards to SOMS is “dicey” and that SOM-related privilege claims should be construed “extremely narrowly”. *See* transcript of 12/6/2018 discovery teleconference at 22:5-10.

⁴ 1/31/2019 Discovery Ruling (“DR”) 14, Part 1 (Doc. No. 1321) at pp. 2-3. (Emphasis in original).

- “[C]ompliance with regulations is usually a business matter, not a legal one”, and materials regarding same are typically not entitled to be withheld as privileged.⁵
- SOMS audit work materials are not entitled to privileged treatment.⁶

These previously established principles apply to the challenged documents as well as any similar documents. Further, any potential privilege was waived as result of Walgreens’ affirmative claims.

Waiver of the Privilege is Applicable

As held in a seminal case from the Second Circuit, and often cited to by the Sixth Circuit, a party may not use a privilege “to prejudice his opponent’s case or to disclose some selected communications for self-serving purposes.” *United States v. Bilzerian*, 926 F.2d 1285, 1292 (2d Cir. 1991).⁷ “Litigants cannot hide behind the privilege if they are relying on privileged communications to make their case” or, more simply, cannot use the privilege as “a shield and a sword.” *In re Lott*, 424 F.3d 446, 454 (6th Cir. 2005) (quoting *Bilzerian*, 926 F.2d at 1292). “[T]he privilege may be implicitly waived when defendant asserts a claim that in fairness requires examination of the protected communications.” *In re United Shore Financial Services, LLC*, 2018 WL 2283893 at *2 (6th Cir. Jan. 3, 2018) (quoting *Bilzerian*, 926 F.2d at 1292). “The waiver may be found even if the privilege holder does not attempt to make use of a privileged communication; he may waive the privilege if he makes factual assertions the truth of which can only be assessed by examination of the privileged communication.” *In re Kidder Peabody Securities. Litigation*, 168 F.R.D. 459, 470 (S.D.N.Y. 1996).⁸

⁵ 6/13/2019 Discovery Ruling 14, Part 9 (Doc. No. 1678) at p. 1.

⁶ 3/31/2019 Discovery Ruling 14, Part 5 (Doc. No. 1498); Discovery Ruling 14, Part 8 (Doc. No. 1666).

⁷ Importantly, the defendant in *Bilzerian* argued that the evidence “he sought to introduce regarding his good faith attempt to comply with the securities laws would not have disclosed the content or even the existence of any privileged communications” *Bilzerian*, 926 F.2d at 1291. However, the 2nd Circuit concluded that an affirmative defense grounded in the defendant’s good faith belief “that he thought his actions were legal would have put his knowledge on the law and the basis for his understanding of what the law required in issue. His conversations with counsel regarding the legality of his schemes would have been directly relevant in determining the extent of his knowledge and, as a result, his intent.” *Id.* at 1292. Consequently, the plaintiff was entitled to discover those “at-issue” communications. *Id.* at 1293–94.

⁸ See also, *Scott v. Chipotle Mexican Grill, Inc.*, 2014 WL 7236907, at *8 (S.D.N.Y. Dec. 18, 2014) (“forfeiture of [] privilege may result where the proponent asserts a good faith belief in the lawfulness of its actions, even without expressly invoking counsel’s advice.”); *Regents of the Univ. of Cal. v. Micro Therapeutics, Inc.*, No. C-03-05669, 2007 WL 2069946, at *3 (N.D. Cal. July 13, 2007) (“Courts frequently conclude that a party waives the protection of the attorney-client privilege when the party voluntarily injects into suit a question that turns on state of mind.”); *Minebea Co. v. Papst*, 355 F.Supp.2d 518, 524 (D.D.C.2005) (“By putting reliance on Papst’s statements in issue, Minebea has opened the door to exploration by Papst of what other persons, documents and information Minebea relied on other than Papst.”); *Baker v. Gen. Motors Corp.*, 209 F.3d 1051, 1055 (8th Cir. 2000) (at-issue waiver is commonly found where “proof of a party’s legal contention implicates evidence encompassed in the contents of an attorney-client communication....”).

As set forth in greater detail below, Walgreens' discovery responses, deposition testimony, and affirmative defenses assert that it fully complied with federal, state, and local statutes and regulations – while at the same time, Walgreens has repeatedly refused to provide details and has claimed privilege over the underlying facts regarding same. By making such affirmative claims, Walgreens has placed the subject matter of any related documents and communications at issue. *See New Phoenix Sunrise Corp. v. C.I.R.*, 408 F. App'x 908, 919 (6th Cir. 2010). Walgreens should not be allowed to, on the one hand, claim that it has met all applicable regulatory requirements, and on the other hand, assert “reliance on counsel” and/or attorney-client privilege over the very information which would allow Plaintiffs to fully examine Walgreens' claims.

I. WALGREENS CLAIMS OF PRIVILEGE – THE “SHIELD”

On the one hand, Walgreens withholds fundamental facts and details about its SOMS and even what it believed or understood its regulatory obligations to be under the CSA. Walgreens has made privilege claims over this information: a) during deposition testimony, and b) by redacting documents and making thousands of privilege claims.

A. Walgreens Hiding of Information in Deposition Testimony

The testimony from Walgreens witness after Walgreens witness was, pursuant to a claim of privilege, withheld or shielded relative to details of: employees' knowledge of its distribution duties under the CSA, its suspicious order monitoring system (“SOMS”), and its SOMS efforts (e.g., policies, procedures, due diligence, suspicious order analysis, audits, etc.). Consequently, many necessary details are unjustly missing. Attached hereto as Exhibit A is a listing of verbatim excerpts from depositions of various Walgreens employees – showing the repeated hiding of critical and fundamental substantive information. The following are just two examples of same.

The December 21, 2018 deposition of Rex Swords (“Swords Dep.”), Walgreens Vice President of Pharmacy Retail Operations and Planning (which included oversight of Pharmaceutical Integrity – responsible for SOMS), illustrates how much of the relevant information is being hidden. *See* Exhibit A at pp.1-2. One of many examples from the Swords Dep. of Walgreens shielding information through the attorney-client privilege is:

“A. I have been instructed not to divulge attorney-client privilege. BY MR. MOUGEY: Q. About your communications with counsel to educate yourself on the details of what Walgreens' suspicious order monitoring policies and procedures were, correct, sir? . . . BY THE WITNESS: A. Again, I've been instructed by my attorney not to divulge the conversations that took place under attorney-client privilege. BY MR. MOUGEY: Q. About suspicious order monitoring policies and procedures at Walgreens, correct, sir? MR. STOFFELMAYR: Objection to the

form. BY THE WITNESS: **A. About many things including those.**” *Id.* See also, Swords Dep. at 225:20-226:14. (Emphasis added).

The above “non-answers” were given in the context of counsel for Walgreens advising the deponent not to disclose any communications with attorneys – preventing plaintiffs from discovering “many things”, including what Walgreens’ past (real-time) positions were relative to its regulatory responsibilities (as a distributor). This was oft repeated throughout the Swords Dep., as well as throughout many other depositions of Walgreens employees. See Exhibit A.

The January 23, 2019 deposition of Tasha Polster (“1/23/19 Polster Dep.”), Director of Pharmaceutical Integrity, also illustrates how much of the relevant information is being hidden. *Id.* at pp. 3-4. Just one example of which includes the following:

Q. “There's no detailed analysis in Pharmaceutical Integrity to make a decision to allow or stop the order as indicated in Mr. Bancroft's memorandum, correct? . . . Q. The order just simply isn't shipped? A. Right, yes. Q. Now, do you see on the "To" Mr. Piñon identified? A. Yes. Q. So, in your meetings with him, you don't ever recall Mr. Piñon advising you and your team that orders flagged by Mr. Bancroft's system were suspicious? MR. HOUTZ: You're calling for advice from an attorney. That's attorney-client privilege information. So, I'd instruct you not to answer what Dwayne Piñon told you or didn't tell you. *Id.* at p. 3. See also, Polster Dep. at 189:1-19.

Walgreens included attorneys in its substantive compliance work in an attempt to insulate details of its SOMS – including the most basic details of what Walgreens employees understood their responsibilities to be under the CSA. This tactic begs the question: If Walgreens witnesses refuse to answer what they understood their obligations to be under the CSA and what the specifics of Walgreens’ SOMS were, how can Walgreens claim that it met all applicable regulatory requirements? Fairness and the jurisprudence dictate that Walgreens not be allowed to do so.

B. Walgreens Specific Privilege Claims

Walgreens’ privilege logs reflect a broad-brush approach over a host of issues. This has manifested in Walgreens claiming privilege over thousands of documents (10,000+) - many of which address the SOMS and compliance related topics which Walgreens has placed “at issue” through its affirmative claims relative to meeting all regulatory requirements. Attached hereto as Exhibit B is a spreadsheet of example Walgreens privilege claims *fully withholding documents* relating to such SOMS and compliance matters – all of which are hereby challenged by the PEC pursuant to prior Discovery Rulings, including but not limited to DR 14-4, 14-5, 14-8 & 14-9.

As can be seen from the “subject” column in the attached spreadsheet, Walgreens’ privilege claims include withholding of documents involving:

“SOM”, “Cardinal High Order Alerts”, “Suspicious Orders survey”,
“Updated SOM Process Flow”, “Controlled Substance Override Form”,
“Monthly Audit Issue Follow-Up”, “CSOS OMP (suspicious ordering) Issue”,
“Weekly Suspicious Ordering Meetings”, “CSOS-Internal Audit Project”,
“Walgreens Compliance Risk Assessment”, and “Walgreens-CAH Due Diligence”.⁹

Walgreens has also *redacted* many documents involving similar SOMS matters pursuant to a claim of privilege. Attached as Exhibit C is a list of some sample documents (with a link to copies of the documents) illustrating these privilege redactions – all of which are hereby challenged by the PEC. Separately attached (and hereby challenged by the PEC) are other documents containing privilege redactions over the following critical SOMS-related matters:

- 12/22/2008 Internal Audit Report regarding “DEA Compliance – Perrysburg Distribution Center” (with attachments). The redactions cover multiple topics, including one of the most central topics in the litigation - “Controlled Drug Reporting”. *See* Exhibit C-1 at pp. 4, 5, 7.
- November 2008 Perrysburg Audit Exit Report regarding (related to the above 12/22/2008 Audit Report). The redactions cover similar topics as those redacted in Exhibit C-1, including the central topic of “Suspicious Control Drug Order Report”. *See* Exhibit C-2 at pp. 1 & 3.
- April 2012 internal email chain between several Walgreens employees (with attorneys and non-attorneys) regarding updates on “Suspicious Order Reporting” and “Rx Supply Chain Contingency Plan for Jupiter”. The primary redaction covers the entirety of the suspicious order reporting (“SOR”) section – which appears to merely set forth facts regarding Walgreens’ SOR policies and/or procedures. *See* Exhibit C-3 at pp. 2-3.
- 7/8/2013 Project Request Form seeking funding for the Rx Integrity Team (responsible for SOMS), listing “PROJECT REQUEST OVERVIEW”, “Project Vision Overview”, and “PROJECT JUSTIFICATION”. The redactions cover the entirety of the project request overview and project justification – which merely provide the description and reasons for the project. *See* Exhibit C-4 at pp. 1-2.

These examples further illustrate how Walgreens is improperly concealing its SOMS and compliance information - using privilege as a shield.

⁹ *See* Exhibit B at “Subject” column.

II. WALGREENS' AFFIRMATIVE CLAIMS/DEFENSES – THE “SWORD”

One the other hand, Walgreens makes various affirmative claims that it has met all pertinent regulatory requirements. Walgreens has made these claims through: a) written discovery responses, b) deposition testimony, and c) affirmative defenses.

A. Walgreens' Affirmative Claims in Written Discovery Responses

Walgreens' December 21, 2018 supplemental discovery responses generally state that the company “has always complied” with the laws and regulations regarding the reporting of suspicious orders to the DEA. Walgreens also repeatedly asserts that its SOMS were based upon “its best understanding of DEA guidance” and/or “DEA’s changing guidance”. The PEC provides just some examples which typify Walgreens' affirmative claims set forth in its discovery responses:

Walgreens **has always complied** with relevant statutes, regulations, and its best understanding of DEA guidance **regarding the identification and reporting of potentially suspicious orders**.¹⁰

Walgreens' methodology for reporting potentially suspicious orders to DEA **has evolved over time to reflect DEA's changing guidance and Walgreens' changing understanding of DEA's expectations**. Walgreens **has always worked** to strike the right balance between (a) providing patients with FDA-approved medications pursuant to prescriptions written for a legitimate medical purpose and (b) **preventing suspicious orders from being filled and shipped to Walgreens pharmacies**.¹¹

Starting in 2012, **Walgreens changed its method of identifying potentially suspicious orders, based on changed guidance from the DEA, changes in industry practice, and Walgreens' development of a new suspicious order monitoring system** that, in 2012, flagged orders of controlled substances based on algorithms for tolerance (i.e., limits on the size of an individual store order for an individual drug) and ceiling limits (i.e., limits on the overall quantity of an individual drug that a single store could purchase over a specified time period).¹²

Walgreens **has always followed the law, regulations, and its best understanding of DEA's guidance on monitoring and reporting of potentially suspicious**

¹⁰ See Exhibit D (Walgreens' 12/21/2018 Supplemental Combined Discovery Responses), at p. 13. (Emphasis added).

¹¹ *Id.* at pp. 13-14 (Emphasis added).

¹² *Id.* at p. 15. (Emphasis added).

orders, as that guidance has changed over time and as reflected in Walgreens' responses to Requests....¹³

B. Walgreens' Affirmative Claims in Deposition Testimony

Walgreens' 30(b)(6) deposition testimony affirmatively asserts that the company has always believed that it complied with the laws and regulations regarding SOM duties. Walgreens also asserts that it has properly monitored and reported suspicious orders, and that it relied on DEA representations regarding same. Pursuant to "at issue" waiver jurisprudence, such affirmative claims waive any attorney-client privilege for communications involving any SOMS-related work. Some deposition excerpts which typify Walgreens' affirmative claims include:

"Walgreens, we always are seeking to be compliant and meet the requirements of the DEA." *See* Exhibit E (12/16/2018 Walgreens 30(b)(6) Deposition, at 127:6-7.

"[W]e can always try to comply with the relevant regulations and requirements." *Id.* at 129:17-18.

"I'm unsure as to the legal requirements, but I believe that, as I said, we work to comply with the relevant regulations." *Id.* at 131:16-18.

"My understanding is that we were reporting those based off of the -- the recommendation of the DEA and the E-3 saying only a computer system can accomplish this." *Id.* at 165:13-16.

"I'm not sure that that's true based on the use of the "and/or" and, additionally, based on guidance that we received from DEA field offices that said that we should be submitting reports regarding II through V substances using this formula." *Id.* at 178:13-18.

"I believe that we thought that that was sufficient to meet the regulatory requirements." *Id.* at 189:12-13.

C. Walgreens' Answer & Affirmative Defenses

Similar to its discovery responses and corporate deposition testimony, Walgreens' affirmative defenses repeatedly assert that the company has always complied with all relevant statutes, regulations and industry standards. Walgreens has specifically and affirmatively claimed that its conduct conformed with the Controlled Substances Act, DEA regulations and other relevant standards, and it has repeatedly couched its compliance in terms of the "state of the art" or "state of knowledge" at the relevant times. The following are some of the affirmative defenses

¹³ *Id.* at pp. 17, 18, 19 (Emphasis added).

(“ADs”) raised in Walgreens’ Answer and Affirmative Defenses (Doc. #: 1257) (hereafter “WAG’s A&ADs”), which support a finding of waiver:

Walgreens’ conduct conformed with the FDCA and the requirements of the FDA, and **the activities of Walgreens alleged in the Complaint conformed with all state and federal statutes, regulations, and industry standards** based on the state of knowledge at the relevant time(s) alleged in the Complaint. *See* WAG’s A&ADs at p. 185, Fifty-Ninth Defense. (Emphasis added).

...**WALGREENS is not liable for damages because the methods, standards, or techniques of designing, manufacturing, labeling, and distributing of the prescription medications at issue complied with and were in conformity with the laws and regulations of the Controlled Substances Act, the FDCA, and the generally recognized state of the art in the industry at the time the product was designed, manufactured, labeled, and distributed.** *See* WAG’s A&ADs at p. 186, Sixty-Sixth Defense. (Emphasis added).

WALGREENS appropriately, completely, and fully performed and discharged any and **all obligations and legal duties** arising out of the matters alleged in the Complaint. *See* WAG’s A&ADs at p. 187, Sixty-Ninth Defense. (Emphasis added).

In this case, Walgreens alleges facts to support an affirmative defense that it met all requirements under the CSA, but it does not want to provide Plaintiffs with the underlying facts and documents. Walgreens has put its SOMS and compliance related documents and communications (including advice of counsel) “at issue” in the litigation – waiving any potential privilege claims. Similarly, Walgreens asserts that its conduct was based, at least in part, on “its best understanding of DEA guidance” and/or “changed guidance from the DEA” – also waiving privilege.¹⁴ Such affirmative allegations made by Walgreens “in fairness requires examination of the protected communications.” *United Shore Financial Services, LLC*, 2018 WL 2283893 at *2.

The Special Master’s prior Discovery Rulings (including those outlining that regulatory compliance is primarily a business function and that audit materials are typically not privileged), support a finding that the documents at issue are not entitled to privileged treatment in the first

¹⁴ *United States v. Exxon Corp.*, 94 F.R.D. 246, 249 (D.D.C.1981) (claim of good faith reliance on governmental representations waived attorney-client privilege – “Exxon has waived its attorney-client privilege by raising the defense of good faith reliance on DOE’s representations” and “because the waiver is generated by the injection of an entire defense, the magnitude of the waiver must be proportionately larger.”). The *Exxon* court concluded that the defendant had waived its attorney-client privilege, stating that Exxon’s claims “do not solely relate to the ‘objective’ representations of [the government] but directly concern Exxon’s subjective interpretation and understanding of those representations; i.e., Exxon’s corporate state of mind.” *Id.* at 248–49.

place.¹⁵ Further, even if the documents were privileged, Judge Polster's 11/21/2018 order,¹⁶ 6th Circuit jurisprudence,¹⁷ and fairness, dictate that when Walgreens makes the affirmative claims which it has repeatedly alleged, it needs to turn over related documents, including allegedly privileged SOMS-related communications, underlying those claims.

Thank you for your attention to this matter.

Sincerely,

/s/ Anthony D. Irpino

Attachments

cc: (via email only)
Defense Counsel
Plaintiff Counsel
Pearl Robertson
Peter Mougey
Jeff Gaddy
Laura Dunning
Page Poerschke
Hunter Shkolnik

¹⁵ See e.g., Discovery Ruling Nos. 14-5 (Doc. No. 1498), 14-8 (Doc. No. 1666) and 14-9 (Doc. No. 1678).

¹⁶ See 11/21/2018 Order (Doc No. 1147), at p. 1, ¶1.

¹⁷ See e.g., *New Phoenix Sunrise Corp.*, 408 F. App'x at 919.